

Exhibit 10

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IN RE:

PELVIC MESH/GYNECARE

LITIGATION

- - -
:SUPERIOR COURT OF

:NEW JERSEY

:LAW DIVISION -

:ATLANTIC COUNTY

:

:MASTER CASE 6341-10

:

:CASE NO. 291 CT

- - -
CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF
CONFIDENTIALITY
- - -

September 18, 2012

VOLUME III
- - -

Transcript of the continued deposition of PIET HINOUL, M.D., Ph.D., called for Videotaped Examination in the above-captioned matter, said deposition taken pursuant to Superior Court Rules of Practice and Procedure by and before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter, Certified Court Reporter, and Notary Public for the State of New Jersey, at the offices of Riker Danzig Scherer Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, commencing at 10:16 a.m.

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1 breaks, if it unravels.

2 BY MR. SLATER:

3 Q. Turn to page 35, if you could. At
4 the top of page 35 it states, "Polypropylene can
5 suffer from degradation following implant."

6 Do you see that?

7 A. Yes.

8 Q. That's something medical affairs is
9 aware of. Correct?

10 MR. SNELL: Objection, form.

11 THE WITNESS: To the best of my
12 knowledge, these products don't degrade.

13 BY MR. SLATER:

14 Q. Were you ever aware that there were
15 people within Ethicon that had been advised through
16 this report that the material used in the Prolift®
17 could degrade after implanted in the body?

18 A. As I stated before, you know, we've
19 got decades of experience with this material. And
20 we use it in cardiac surgery. People would fall
21 dead on the street if it would degrade.

22 MR. SLATER: Move to strike.

23 BY MR. SLATER:

24 Q. Were you ever -- well, rephrase.

25 Was medical affairs aware that there

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1 were people within Ethicon, or Ethicon's affiliates,
2 that were made aware that the mesh used in the
3 Prolift® was subject to degradation once implanted
4 in the woman's body?

5 MR. SNELL: Objection, form.

6 THE WITNESS: No. The mesh does not
7 degrade.

8 MR. SLATER: Move to strike after
9 "no."

10 BY MR. SLATER:

11 Q. You would agree with me that if
12 it could be -- well, rephrase.

13 You would agree with me that if the
14 Prolift® mesh were to degrade, that that could
15 increase the risk for complications?

16 MR. SNELL: Objection, form.

17 THE WITNESS: What kind of
18 complication would you be referring to? Recurrence
19 because it degrades can --

20 BY MR. SLATER:

21 Q. For example, recurrence or a more
22 intense foreign body reaction?

23 A. But we understand the foreign body
24 reaction very well for Prolene®. Right.

25 Q. If there were degradation, that could

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1 fuel a more intense inflammatory reaction. Correct?

2 A. We would have seen it.

3 Q. Well, there may be a difference of
4 opinion about whether or not it was occurring and
5 whether it was noticed or not. So what I'm asking
6 you is this.

7 If degradation of the Prolift® mesh
8 were to occur, you would agree that could increase
9 the risk for complications occurring?

10 A. The majority of people would agree
11 with me that it doesn't degrade and that we were
12 very well -- that we understand the inflammatory
13 process very well after implantation of the Prolift®
14 mesh.

15 MR. SLATER: Move to strike.

16 Just could you read my question back?

17 - - -

18 (The court reporter read the
19 pertinent part of the record.)

20 - - -

21 MR. SNELL: Objection, form.

22 THE WITNESS: It doesn't occur, so I
23 cannot answer the question.

24 BY MR. SLATER:

25 Q. Ethicon never expected the mesh used

1 in the Prolift® to degrade. Correct?

2 A. Correct.

3 Q. Ethicon never factored the potential
4 for degradation into the risk/benefit analysis.
5 Correct?

6 MR. SNELL: Objection, form.

7 THE WITNESS: Correct.

8 MR. SNELL: Was that question
9 risk/benefit analysis?

10 MR. SLATER: (Counsel nods head.)

11 MR. SNELL: Okay. Sorry.

12 BY MR. SLATER:

13 Q. If it could be shown to you that the
14 Prolift® mesh does degrade to some extent --

15 A. Uh-huh.

16 Q. -- then you certainly would believe
17 that that could increase the risk for complications.
18 Correct?

19 A. I think you're questioning my
20 understanding of the inflammatory response to the
21 mesh, and it wouldn't affect my --

22 Q. I'm just talking in general.

23 A. So am I.

24 Q. That in general, if there were
25 degradation of the Prolift® mesh, that could

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1 increase the risk for complications, whatever
2 complications that may be?

3 MR. SNELL: Objection, form.
4 Go ahead.

5 THE WITNESS: It's hypothetical.

6 BY MR. SLATER:

7 Q. It's hypothetical?

8 A. Right. So if it would cure cancer,
9 you know, that would also be a nice feature.

10 Q. Well, it would be a bad feature if
11 degradation were to be shown. Correct?

12 MR. SNELL: Objection.

13 THE WITNESS: If it --

14 BY MR. SLATER:

15 Q. That would be a bad thing. Right?

16 A. If it could be objectified, yeah.

17 Q. It would increase the risk for
18 complications if it were to be shown it could
19 happen. Correct?

20 MR. SNELL: Same objection.

21 THE WITNESS: I don't know.

22 MR. SLATER: Just turn the video off
23 for a second.

24 THE VIDEOGRAPHER: Going off the
25 video at 12:29.

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1 "monofilament implants" -- which would include the
2 Prolift®. That's the type of mesh in the Prolift®.
3 Correct?

4 A. Yes.

5 Q. -- "were more frequently associated
6 with sclerosis than other" polypropylene "and
7 composite implants, 20% versus 0%, respectively."

8 That was one of their findings.

9 Correct?

10 A. Right. But you've got to remember
11 that these are pieces of mesh taken out of patients
12 with an issue, so there's a bias there.

13 Q. Well, what they're studying is what
14 has happened to the mesh in cases where women
15 suffered complications that resulted in the need to
16 explant the mesh. Correct?

17 A. Yes.

18 Q. So this gives very valuable
19 information about what is happening to those women
20 who suffer complications serious enough to require
21 removal of mesh. Correct?

22 MR. SNELL: Objection, form.

23 THE WITNESS: It gives us
24 information, yes.

25 BY MR. SLATER:

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1 Q. And they found degradation of the
2 implants in multiple cases, if you look at the "SEM
3 analysis" just below what I just read. Correct?

4 A. That's what they claim, yes.

5 Q. And they actually say over on the
6 next column, the very end of that paragraph,
7 "Evidences of" polypropylene "degradation were more
8 frequently observed when the surrounding tissue
9 reaction was classified as infection (59% of
10 degraded" polypropylene "samples with type 1
11 reaction versus 20% for type 3 reaction."

12 Do you see that?

13 A. Yes.

14 Q. If you could go to page 267, the
15 right-hand column, the top paragraph starts out,
16 "The chronic inflammatory reaction." Do you see
17 that? Page 267, the number is at the top right.
18 You've got the page.

19 A. Yep.

20 Q. Right-hand column top paragraph.
21 There's a discussion about how they believe this
22 degradation can occur.

23 Do you see that?

24 MR. SNELL: Objection, form.

25 THE WITNESS: Yep.

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1 BY MR. SLATER:

2 Q. Has anyone within medical affairs at
3 Ethicon ever tried to figure out if there's any
4 validity to this position as described here?

5 MR. SNELL: Objection, form.

6 THE WITNESS: Yes. We had
7 discussions with our polymer scientists on this
8 issue, and they refer to the many years of data and
9 the inertness of our polypropylene and our Prolene®
10 sutures. And they also refer to the fact that these
11 were not your standard conditions. And I think the
12 data is too limited to infer firm conclusions on it.

13 BY MR. SLATER:

14 Q. That was the conclusion medical
15 affairs drew?

16 A. Yes. We did not feel it changed our
17 position on the inertness of the mesh under normal
18 conditions.

19 Q. I want to look a little bit at what
20 the authors wrote on page 268, left column.

21 A. 268.

22 Q. 268?

23 A. Yep.

24 Q. "Polypropylene, in particular," one
25 of the types of polypropylene which they called

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1 "LDPPMF, is the most used material in the" pelvic
2 floor disorder "surgery. It is generally considered
3 an inert material. This study contradicts this
4 established fact and confirms the results of other
5 studies on" polypropylene "materials used in other
6 areas of medical specialization."

7 Do you see that?

8 A. Right. Uh-huh.

9 Q. And then a little further down they
10 say, "These studies showed that" polypropylene
11 "meshes undergo degradation while in vivo, most
12 likely due to fatty acids diffusion...or oxidation
13 with formation of carboxyl groups."

14 Do you see that?

15 A. Yes.

16 Q. So the authors took this explanted
17 mesh and put it through a rigorous analysis of
18 various types of testing, and they were able to
19 document that the mesh -- the polypropylene mesh was
20 degraded, and then they offered their opinions as to
21 what is likely leading to that degradation.

22 Correct?

23 MR. SNELL: Objection, form.

24 THE WITNESS: They hypothesize. They
25 clearly state that they are the one article over

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1 decades of articles that differ with them.

2 BY MR. SLATER:

3 Q. Now, in this study, you would have to
4 agree with me, they did a very thorough job of
5 making sure that they applied a rigorous and
6 multi-faceted analysis of the explanted mesh so
7 that they could determine whether or not the mesh
8 was degraded. Right?

9 MR. SNELL: Objection, form.

10 THE WITNESS: If you would want to
11 study this rigorously, you would try and have
12 explants of normal, you know, nonexposed,
13 nonpathological conditions of polypropylene mesh.

14 BY MR. SLATER:

15 Q. What they established was that in
16 mesh in complication patients, where the mesh needed
17 to be removed, that their multi-faceted study and
18 the various tests they did demonstrated degradation
19 of the polypropylene mesh. Correct?

20 MR. SNELL: Objection, form.

21 BY MR. SLATER:

22 Q. That's their finding. Right?

23 MR. SNELL: Same objection.

24 THE WITNESS: Yes. And they
25 hypothesize that.

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1 BY MR. SLATER:

2 Q. They hypothesize the reason why it
3 happens, but they definitely documented the
4 degradation. Correct?

5 MR. SNELL: Same objection.

6 THE WITNESS: That's their
7 hypothesis.

8 BY MR. SLATER:

9 Q. They documented the degradation but
10 offered a hypothesis as to why it occurs. Correct?

11 MR. SNELL: Same objection.

12 THE WITNESS: Yes.

13 BY MR. SLATER:

14 Q. In fact, in the conclusion, which is
15 on the second to last page of the document, they say
16 in part, this is starting on the first paragraph
17 about halfway down, "This study, however, brings in
18 to question the prevailing understanding of"
19 polypropylene "as inert when used in vaginal surgery
20 for pelvic floor repair procedures."

21 Certainly when you read this article,
22 you felt that the study did in fact raise serious
23 questions about whether polypropylene is inert.
24 Correct?

25 A. Well, maybe it was secondary to the

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1 process they used to clean the meshes and things.
2 So I think there's a lot of questions around this
3 paper that remain unanswered. I would like to defer
4 these to my preclinical colleagues, because I do not
5 believe that this has changed the medical
6 perspective across the world on the inertness of
7 polypropylene.

8 Q. They state in the second paragraph of
9 their conclusion, "In this work, not all types of"
10 polypropylene "implants degraded equally. The"
11 polypropylene "implants degraded more in the
12 presence of an acute infection or chronic
13 inflammation."

14 Do you see that?

15 A. Yes.

16 Q. And certainly that makes sense to
17 you, that you would have more degradation if there
18 was an acute infection or chronic inflammation.
19 Correct?

20 MR. SNELL: Objection, form.

21 THE WITNESS: It's their hypothesis,
22 yes. They're entitled to their hypothesis.

23 BY MR. SLATER:

24 Q. I've just marked as Exhibit 884 --

25 - - -